

**Remarks:**

**1. Status of Application**

As currently amended, claims 1-16 are pending and claim 9 has been withdrawn. Claim 17 is cancelled by this Amendment without prejudice to the prosecution of its subject matter in future applications. Claim 9 is withdrawn from prosecution in accordance with applicants' election of December 19, 2006 without prejudice to prosecution of its subject matter in future applications.

In an Office Action of April 12, 2007 ("the Office Action") claim 1 - 8 and 9 - 17 were rejected and the use of trademarked terms in applicants' specification was objected to.

With this response, applicants submit a substitute specification in which all references to trademarks are amended to obviate the objections to the original specification and claim 17 is cancelled.

With respect to the remaining claims, claims 1-8 and 10-16 have been rejected as unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,147,122 to Mirejovsky et al. ("Mirejovsky") in view of pp. 656 - 694 of Busta, *Disinfection, Sterilization, and Preservation*, Third Edition, Ed SS. Block, 1983, Published by Lea and Febiger, Philadelphia, USA ("Busta"), further in view of pp. 329-344 of Bulet, *Antimicrobial peptides in insects; structure and function*, Developmental and Comparative Immunology, 23 (1999) pp. 329-344 ("Bulet"), and still further in view of U.S. Patent No. 7,097,849 to Mishra et al. ("Mishra").

Claims 1, 11, and 17 have been provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 3, 18, and 30 of copending Application No. 10/677,747 published as US 2004/0220283 and claims 1, 49, 66, 71-72, and 77 of copending Application No. 10/766,631 published as US 2004/0265388 and claim 1 of copending Application No. 10/629,308 published as US 2005/0027019 in view of Mirejovsky, further in view of Busta, further in view of Mishra, and further in view of Thompson.

**2. Response to the Rejection of Claims 1-8 and 10-16 under 35 U.S.C. § 103(a)**

As stated above, the Office Action has rejected claims 1-8 and 10-16 as obvious over Mirejovsky further in view of three references: Busta, Bulet and Mishra. Applicants respectfully traverse this rejection.

Applicants' claim 1 recites a pharmaceutical composition comprising propofol and cysteine. As the Office Action stated, "Mirejovsky et al. teach a propofol composition

containing sulfite as an antimicrobial agent." Mirejovsky teaches propofol compositions formulated as oil-in-water emulsions that include sulfite, and only sulfite, as an antimicrobial agent. Mirejovsky says nothing, however, with respect to cysteine, and therefore does not teach cysteine as a component of a pharmaceutical composition.

The Office Action next relies upon the Busta reference (p. 671) for its purported teaching "that sulfites exert their antimicrobial effects by interaction with structural proteins."

As a preliminary matter, Busta discusses *food* preservatives not pharmaceutical preservatives. Moreover, Busta itself explicitly states that how sulfites work as a preservative is *not known*:

the precise cause of inhibition or death [of bacteria] may not always be known. Cell damage **may** result from interaction with thiol groups in structural proteins, enzymes, cofactors, vitamins, nucleic acids, and lipids.

Busta, p. 671, first full paragraph (citation omitted, emphasis added). Thus, whatever value Busta may be to a food chemist working with food preservatives, one skilled in the anesthetic art would not likely expect a similar reaction in the anesthetic art, particularly since Busta's suggestion of how sulfites may react chemically to exert antimicrobial action is speculative.

The Office Action next relies upon the Bulet reference for its disclosure that certain insect *peptides containing cysteine* have antimicrobial properties. Bulet, pp. 330, 332. Bulet is a study of selected immunological mechanisms of insects. Bulet, abstract. Bulet does not teach that cysteine itself has antimicrobial activity nor does it suggest that cysteine would have antimicrobial properties in other environments. Most importantly, it does not suggest that, whatever antimicrobial properties it ascribes to the insect peptides containing cysteine, these properties necessarily result in a chemically similar reaction to any of those speculatively suggested in Busta. For these reasons, Busta does not teach or suggest cysteine in a pharmaceutical composition nor would it provide one skilled in the art with a reasonable expectation of success in applying cysteine as claimed in applicants' claim 1.

Finally, although the Office Action did not appear to rely upon Mishra in its rejection of applicants' claim 1, Mishra too is silent with respect cysteine as a component of a pharmaceutical composition.

Applicants respectfully submit that the cited prior art fails to teach or suggest each of the limitations of applicants' invention as recited in claim 1, in particular cysteine as a component of a pharmaceutical composition comprising propofol, and therefore cannot serve

as grounds for a proper prima facie case of obviousness. Assuming, for the sake of argument that cysteine as a component of a pharmaceutical composition was suggested, one skilled in the art would have had no reasonable expectation of success in formulating applicants' invention as claimed in claim 1. For all these reasons, applicants respectfully request that this rejection be withdrawn.

The remaining rejected claims 2-8 and 10-16 depend directly or indirectly from claim 1 and incorporate each of its limitations. While there may be other independent reasons why these claims (individually or collectively) are patentable, applicants urge that they are patentable for the same reasons claim 1 is patentable. Accordingly, applicants respectfully request that the 35 U.S.C. 103 rejection of these claims also be withdrawn.

### **3. Response to the Rejection of Claims 1, 11, and 17 Under Double Patenting**

Finally, as summarized above, the Office Action also provisionally rejected claims 1, 11, and 17 for obviousness-type double patenting over Application No. 10/629,308, Application No. 10/677,747 and Application No. 10/766,631 further in view of Mirejovsky, Busta, Bulet, and Thompson. Applicants will address this rejection, if needed, when the claims of this application have been deemed otherwise allowable, or one or more of the copending applications have issued or been allowed, and this rejection has been made final.

### **4. Summary**

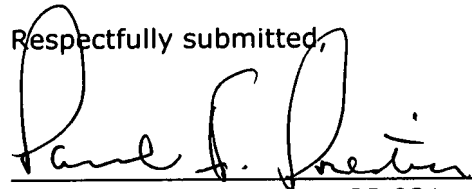
Applicants have obviated the objections to their specification and the 35 U.S.C. 102(e) rejection of claim 17 by this amendment and have deferred consideration of the provisional rejection of claim 1, 11 and 17. With respect to the 35 U.S.C. 103 rejection of claims 1 - 8 and 10 - 16, applicants contend that, upon reconsideration, this rejection should be withdrawn inasmuch as the prior art relied upon does not provide the factual foundation necessary to support the rejection.

Appln. No.: 10/695,291  
Amendment Dated July 11, 2007  
Reply to Office Action of April 12, 2007

J&J-102US

The examiners in charge of this application are invited to call applicants' undersigned attorneys if there is any question about this response or if it appears that there remain other impediments to allowance of applicants' claims and these impediments may be resolved by Examiner's Amendment.

Respectfully submitted,



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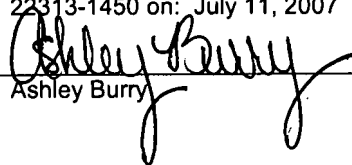
Attachments: Substitute Specification (clean and marked copies)

Dated: July 11, 2007

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Ashley Burry

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